BioLineRx Reports First Quarter 2019 Financial Results and Provides Corporate Update

May 14, 2019

On track for Phase 2 data read-outs in pancreatic cancer and consolidation AML by year-end 2019
Management to hold conference call today, May 14, at 10:00 am EDT

TEL AVIV, Israel, May 14, 2019 /PRNewswire/ -- BioLineRx Ltd. (NASDAQ: BLRX) (TASE: BLRX), a clinical-stage biopharmaceutical company focused on oncology, today reports its financial results for the quarter ended March 31, 2019 and provided a corporate update.

Highlights and achievements during the first quarter 2019 and subsequent period:

- Presented successful engraftment data from Phase 3 GENESIS trial of BL-8040 in multiple myeloma patients at 45th Annual Meeting of European Society for Blood and Marrow Transplantation. These data follow previously announced successful mobilization data which led the Data Monitoring Committee to recommend proceeding to the randomized placebo-controlled Part 2 of the study.
- Received FDA Orphan Drug Designation for BL-8040 for the treatment of pancreatic cancer. This is an addition to prior orphan drug designations that have been granted for BL-8040 in AML and stem cell mobilization.
- Received approval from the FDA for Investigational New Drug (IND) application for AGI-134, which will enable expansion of the ongoing Phase 1/2a study, currently being carried out in the UK and Israel, to the US by the first half of 2020.

"As we progress through 2019, we are approaching important data milestones with our lead program, the CXCR4 antagonist BL-8040, in two cancer indications with high unmet medical need," said Philip Serlin, Chief Executive Officer of BioLineRx. "In pancreatic cancer, an extremely difficult cancer indication to treat, we are optimistic that we can build upon the encouraging results that we observed in the dual combination arm of our ongoing COMBAT/KEYNOTE-202 Phase 2a study of BL-8040 and Merck's KEYTRUDA with the addition of chemotherapy, and we are eager to see top-line results for the triple combination arm of the study by the end of this year. Similarly, in consolidation AML, we look forward to important data from our Phase 2b trial that will help inform later stage development of this promising program."

"In parallel, our second clinical candidate, AGI-134, is progressing through a phase 1/2a clinical trial, and we anticipate initial safety data later this year as we look to efficiently advance this promising candidate into the second part of the study where we can assess efficacy in multiple tumor types. We continue to execute on our clinical development plan, and believe these upcoming data readouts can drive near-term value creation while generating additional partnering interest," Mr. Serlin concluded.

Expected significant milestones through end of 2019 and early 2020:

- Top-line results from the Phase 2 triple combo pancreatic cancer trial of BL-8040, KEYTRUDA and chemotherapy under the Company's collaboration with Merck in the second half of 2019;
- Potential interim results from the Phase 2 AML consolidation study in the second half of 2019;
- Initial safety results from part 1 of the Phase 1/2a trial of AGI-134 in the second half of 2019;
- Top-line results from one or more of the ongoing solid tumor trials under the Company's collaboration with Genentech, potentially by the end of 2019 or early 2020.

Financial Results for the Quarter Ended March 31, 2019

Research and development expenses for the quarter ended March 31, 2019 were $4.4 million, a decrease of $0.7 million, or 13.4%, compared to $5.1 million for the comparable period in 2018. The decrease resulted primarily from a decrease in share-based compensation.

Sales and marketing expenses for the quarter ended March 31, 2019 were $0.3 million, a decrease of $0.2 million, or 47%, compared to $0.5 million for the comparable period in 2018. The decrease resulted primarily from a one-time compensation payment in the 2018 period, as well as a decrease in share-based compensation.

General and administrative expenses for the quarter ended March 31, 2019 were $0.9 million, a decrease of $0.2 million, or 13.5% compared to $1.1 million for the comparable period in 2018. The decrease resulted primarily from a decrease in share-based compensation.

The Company's operating loss for the quarter ended March 31, 2019 amounted to $5.6 million, compared with an operating loss of $6.6 million for the comparable period in 2018.

Non-operating expenses amounted to $0.3 million for the quarter ended March 31, 2019, compared with non-operating income of $0.5 million for the comparable period in 2018. Non-operating expenses for the three months ended March 31, 2019 primarily relate to warrant offering expenses offset by fair-value adjustments of warrant liabilities on our balance sheet. Non-operating income for the three months ended March 31, 2018 primarily relate to fair-value adjustments of warrant liabilities on our balance sheet. These fair-value adjustments were highly influenced by the Company's share price at each period end (revaluation date).

Net financial expenses amounted to $0.2 million for the quarter ended March 31, 2019 compared to an immaterial amount of net financial expenses for the three months ended March 31, 2018. Net financial expenses for the 2019 period primarily relate to interest paid on loans, offset by investment income earned on bank deposits. Net financial expenses for the 2018 period primarily relate to losses recorded on foreign currency hedging transactions, offset by investment income earned on bank deposits.

The Company's net loss for the quarter ended March 31, 2019 amounted to $6.2 million, similar to the comparable period in 2018.

The Company held $40.6 million in cash, cash equivalents and short-term bank deposits as of March 31, 2019.

Net cash used in operating activities was $4.6 million for the three months ended March 31, 2019, compared with net cash used in operating activities of $6.8 million for the three months ended March 31, 2018. The $2.2 million decrease in net cash used in operating activities during the three-month period in 2019, compared to the three-month period in 2018, was primarily the result of changes in operating asset and liability items between the two periods – i.e., a decrease in prepaid expenses and other receivables in 2019 versus an increase in 2018, as well as a decrease in accounts payable and accruals in 2018.

Net cash used in investing activities was $9.3 million for the three months ended March 31, 2019, compared to net cash provided by investing activities of $8.1 million for the three months ended March 31, 2018. The changes in cash flows from investing activities relate primarily to investments in, and maturities of, short-term bank deposits.

Net cash provided by financing activities was $14.9 million for the three months ended March 31, 2019, compared to net cash provided by financing activities of $1.4 million for the three months ended March 31, 2018. The increase in cash flows from financing activities reflects the underwritten public offering completed in February 2019.

Conference Call and Webcast Information

BioLineRx will hold a conference call today, May 14, 2019 at 10:00 a.m. EDT. To access the conference call, please dial +1-888-281-1167 from the U.S. or +972-3-918-0644 internationally. The call will also be available via webcast and can be accessed through the Investor Relations page of BioLineRx's website. Please allow extra time prior to the call to visit the site and download any necessary software to listen to the live broadcast.

A replay of the conference call will be available approximately two hours after completion of the live conference call on the Investor Relations page of BioLineRx's website. A dial-in replay of the call will be available until May 16, 2019; please dial +1-888-782-4291 from the U.S. or +972-3-925-5925 internationally.

(Tables follow)

About BioLineRx

BioLineRx is a clinical-stage biopharmaceutical company focused on oncology. The Company in-licenses novel compounds, develops them through pre-clinical and/or clinical stages, and then partners with pharmaceutical companies for advanced clinical development and/or commercialization.

BioLineRx's leading therapeutic candidates are: BL-8040, a cancer therapy platform, which has successfully completed a Phase 2a study for relapsed/refractory AML, is in the midst of a Phase 2b study as an AML consolidation treatment and a Phase 3 study in stem cell mobilization for autologous transplantation; and AGI-134, an immunotherapy treatment in development for multiple solid tumors, which is being investigated in a Phase 1/2a study. In addition, BioLineRx has a strategic collaboration with Novartis for the co-development of selected Israeli-sourced novel drug candidates; a collaboration agreement with MSD, on the basis of which the Company is conducting a Phase 2a study in pancreatic cancer using the combination of BL-8040 and KEYTRUDA® (pembrolizumab), and a collaboration agreement with Genentech, a member of the Roche Group, to investigate the combination of BL-8040 and Genentech's atezolizumab in several Phase 1b/2 studies for multiple solid tumor indications and AML.

For additional information on BioLineRx, please visit the Company's website at www.biolinerx.com, where you can review the Company's SEC filings, press releases, announcements and events. BioLineRx industry updates are also regularly updated on Facebook, Twitter, and LinkedIn.

Various statements in this release concerning BioLineRx's future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Some of these risks are: changes in relationships with collaborators; the impact of competitive products and technological changes; risks relating to the development of new products; and the ability to implement technological improvements. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 28, 2019. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF FINANCIAL POSITION

(UNAUDITED)

	December 31, 2018	March 31, 2019

	in USD thousands	
Assets		
CURRENT ASSETS		
Cash and cash equivalents	3,404	4,384
Short-term bank deposits	26,747	36,224
Prepaid expenses	488	583
Other receivables	1,339	458
Total current assets	31,978	41,649
NON-CURRENT ASSETS		
Long-term prepaid expenses	56	55
Property and equipment, net	2,227	2,143
Right-of-use assets	-	1,797
Intangible assets, net	21,972	21,950
Total non-current assets	24,255	25,945
Total assets	56,233	67,594
Liabilities and equity		
CURRENT LIABILITIES		
Current maturities of long-term loans	895	1,636
Accounts payable and accruals:		
Trade	4,493	4,817
Other	1,363	989
Lease liabilities	-	693
Total current liabilities	6,751	8,135
NON-CURRENT LIABILITIES		
Warrants	323	5,213
Long-term loans, net of current maturities	7,838	7,228
Lease liabilities	-	1,130
Total non-current liabilities	8,161	13,571

COMMITMENTS AND CONTINGENT LIABILITIES		
Total liabilities	14,912	21,706
EQUITY		
Ordinary shares	3,110	3,928
Share premium	250,192	259,860
Capital reserve	11,955	12,191
Other comprehensive loss	(1,416)	(1,416)
Accumulated deficit	(222,520)	(228,675)
Total equity	41,321	45,888
Total liabilities and equity	56,233	67,594

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF COMPREHENSIVE LOSS

(UNAUDITED)

	Three months ended March 31,	
	2018	**2019**
	in USD thousands	
RESEARCH AND DEVELOPMENT EXPENSES	(5,070)	(4,392)
SALES AND MARKETING EXPENSES	(484)	(256)
GENERAL AND ADMINISTRATIVE EXPENSES	(1,075)	(930)
OPERATING LOSS	(6,629)	(5,578)
NON-OPERATING INCOME (EXPENSES), NET	462	(340)
FINANCIAL INCOME	175	210
FINANCIAL EXPENSES	(206)	(447)
NET LOSS AND COMPREHENSIVE LOSS	(6,198)	(6,155)
LOSS PER ORDINARY SHARE - BASIC AND DILUTED	(0.06)	(0.05)

WEIGHTED AVERAGE NUMBER OF SHARES USED IN CALCULATION OF LOSS PER ORDINARY SHARE	106,169,273	132,979,984

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CONDENSED CONSOLIDATED INTERIM STATEMENTS OF CHANGES IN EQUITY

(UNAUDITED)

	Ordinary shares	**Share premium**	**Capital Reserve**	**Other comprehensive loss**	**Accumulated deficit**	**Total**
	in USD thousands					
BALANCE AT JANUARY 1, 2018	2,836	240,682	10,337	(1,416)	(199,558)	52,881
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2018:						
Issuance of share capital, net	37	1,386	-	-	-	1,423
Employee stock options exercised	1	29	(30)	-	-	-
Employee stock options forfeited and expired	-	80	(80)	-	-	-
Share-based compensation	-	-	916	-	-	916
Comprehensive loss for the period	-	-	-	-	(6,198)	(6,198)
BALANCE AT MARCH 31, 2018	2,874	242,177	11,143	(1,416)	(205,756)	49,022

	Ordinary shares	**Share premium**	**Capital Reserve**	**Other comprehensive loss**	**Accumulated deficit**	**Total**
	in USD thousands					
BALANCE AT JANUARY 1, 2019	3,110	250,192	11,955	(1,416)	(222,520)	41,321
CHANGES FOR THREE MONTHS ENDED MARCH 31, 2019:						
Issuance of share capital, net	817	9,620	-	-	-	10,437
Employee stock options exercised	1	18	(18)	-	-	1
Employee stock options forfeited and expired	-	30	(30)	-	-	-

Share-based compensation	-	-	284	-	-	284
Comprehensive loss for the period	-	-	-	-	(6,155)	(6,155)
BALANCE AT MARCH 31, 2019	3,928	259,860	12,191	(1,416)	(228,675)	45,888

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CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Three months ended March 31,	
	2018	**2019**
	in USD thousands	
CASH FLOWS - OPERATING ACTIVITIES		
Comprehensive loss for the period	(6,198)	(6,155)
Adjustments required to reflect net cash used in operating activities (see appendix below)	(609)	1,533
Net cash used in operating activities	(6,807)	(4,622)
CASH FLOWS - INVESTING ACTIVITIES		
Investments in short-term deposits	(4,000)	(21,510)
Maturities of short-term deposits	12,167	12,228
Purchase of property and equipment	(54)	(31)
Purchase of intangible assets	(29)	-
Net cash provided by (used in) investing activities	8,084	(9,313)
CASH FLOWS - FINANCING ACTIVITIES		
Issuance of share capital and warrants, net of issuance costs	1,423	14,989
Employee stock options exercised	-	1
Repayments of loans	(23)	(23)

Repayments of lease liabilities	-	(50)
Net cash provided by financing activities	1,400	14,917
INCREASE IN CASH AND CASH EQUIVALENTS	2,677	982
CASH AND CASH EQUIVALENTS – BEGINNING OF PERIOD	5,110	3,404
EXCHANGE DIFFERENCES ON CASH AND CASH EQUIVALENTS	23	(2)
CASH AND CASH EQUIVALENTS - END OF PERIOD	7,810	4,384

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APPENDIX TO CONDENSED CONSOLIDATED INTERIM CASH FLOW STATEMENTS

(UNAUDITED)

	Three months ended March 31,	
	2018	**2019**
	in USD thousands	
Adjustments required to reflect net cash used in operating activities:		
Income and expenses not involving cash flows:		
Depreciation and amortization	140	213
Long-term prepaid expenses	1	1
Exchange differences on cash and cash equivalents	(23)	2
Gain on adjustment of warrants to fair value	(465)	(79)
Share-based compensation	916	284
Warrant issuance costs	-	417
Interest and exchange differences on short-term deposits	(182)	(195)
Interest and linkage differences on loans	(1)	154
	386	797

Changes in operating asset and liability items:		
Decrease (increase) in prepaid expenses and other receivables	(453)	786
Decrease in accounts payable and accruals	(542)	(50)
	(995)	736
	(609)	1,533
Supplemental information on interest received in cash	167	229
Supplemental information on non-cash transaction:		
Initial establishment of right-of-use assets against lease liabilities	-	1,878

Contact:
Tim McCarthy
LifeSci Advisors, LLC
+1-212-915-2564
tim@lifesciadvisors.com

or

Tsipi Haitovsky
Public Relations
+972-52-598-9892
tsipihai5@gmail.com

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